K110999

Section 5 - 510(k) Summary

APR 26 2011

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:

Edan Instruments, Inc.

3/F-B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, Shekou, Nanshan Shenzhen, 518067 P.R. China

Tel.: (0755) 26858736

Fax: (0755) 26882223

Contact Person: Randy Jiang

Prepare date: Feb 06, 2011

2. Device name and classification:

Device Name:

Digital Ultrasonic Diagnostic Imaging System, Model DUS 60

Classification Name:

892.1560 System, Imaging, Pulsed echo, Ultrasonic

Product code: IYO

892.1570 Transducer, Ultrasonic, Diagnostic

Product code: ITX

Regulatory Class: Class II

3. Predicate Device:

DUS 6 Digital Ultrasonic Diagnostic Imaging System / K091680 / Edan Instruments, Inc.

DC-3 Diagnostic Ultrasound System / K081320 / Shenzhen Mindray Bio-medical Electronics Co., Ltd.

4. Device Description:

DUS 60 Digital Ultrasound Diagnostic Imaging System is a portable digital ultrasonic diagnostic system applied in ultrasound diagnostic examination of abdominal, obstetrical, small parts, gynecological, orthopedic, cardiac, and urological applications.

It is designed to produce ultrasound waves into body tissue and to present the returned echo information on the monitor; the resulting information is displayed in the following display modes: B-Mode, M-Mode, B+M Mode and PW Mode. This system controlled by software is a Track 3 device that employs an array of probes that include linear array, convex linear array, microconvex linear array, transrectal and transvaginal with a frequency range of approximately 2.0MHz-10.0MHz.

The system consists of a main unit, a display and transducers.

5. Intended Use: The Digital Ultrasonic Diagnostic Imaging System DUS 60 is intended for diagnostic ultrasound imaging analysis in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The system is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus, Abdomen, Pediatrics, Small Organ, Neonatal Cephalic, Cardiology, Peripheral Vessel, Musculo-skeleton (both Conventional and Superficial), Urology (including prostate), Transrecta and Transvagina.

6. Effectiveness and Safety Considerations:

Clinical Test:
Clinical testing is not required.

Non-clinical Test:
The following safety standards are conducted on the subject device:
(1) IEC 60601-1 and IEC 60601-2-37 Electrical Safety
(2) IEC 60601-1-2 Electromagnetic Compatibility
(3) Acoustic output testing as per the guideline "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008.
(4) ISO 10993-1, ISO 10993-5 and ISO 10993-10

7. Comparison to the Predicate Device

Comparison to the predicate devices, the subject device has the similar technology characteristics and has the same intended use, same design principle, same electrical classification and same accuracy. The mainly difference between the subject device and predicate devices primarily includes physical specifications, display monitor and display mode. All above differences do not affect the usage, safety and effectiveness, and no new question is raised regarding the safety and effectiveness.

8. Substantially Equivalent Determination

The related tests (including safety, EMC, performance and biocompatibility) of the entire device were conducted on the DUS 60 Digital Ultrasonic Diagnostic Imaging System. This premarket notification submission demonstrates that DUS 60 Digital Ultrasonic Diagnostic Imaging System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

APR 2 6 2011

Edan Instruments
% Mr. Marc M. Mouser
Engineering Leader & FDA Office Coordinator
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

Re: K110999
Trade/Device Name: Digital Ultrasonic Imaging Systems, Model DUS 60
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: March 8, 2011
Received: April 11, 2011

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Digital Ultrasonic Imaging Systems, Model DUS 60, as described in your premarket notification:

Transducer Model Number

C363UA	L742UA
C362UA	L763UA
C343UA	E743UA
C321UA	E613UA
L743UA	C613UA

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Section 6 - Indications for Use

510(k) Number (if known):

Device Name: Digital Ultrasonic Diagnostic Imaging System, Model DUS 60

The Digital Ultrasonic Diagnostic Imaging System DUS 60 is intended for diagnostic ultrasound imaging analysis in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The system is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus, Abdomen, Pediatrics, Small Organ, Neonatal Cephalic, Cardiology, Peripheral Vessel, Musculo-skeleton (both Conventional and Superficial), Urology (including prostate), Transrecta and Transvagina.

Prescription Use ___X___ Or Over the Counter Use _____

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Mary S Pastel

(Division Sign-Off)

Division of Radiological Devices

Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K110999

Diagnostic Ultrasound Indications for Use Form

DUS 60 Digital Ultrasonic Diagnostic Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N	N			N	Note 1
Abdominal	N	N	N			N	Note 1
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify)	N	N	N			N	Note 1
Neonatal Cephalic	N	N	N			N	Note 1
Adult Cephalic							
Transrectal	N	N	N			N	Note 1
Transvaginal	N	N	N			N	Note 1
Transurethral							
Musculo-skeletal (**Conventional**)	N	N	N			N	Note 1
Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1
Intravascular							
Cardiac	N	N	N			N	Note 1
Intravascular							
Peripheral vascular	N	N	N			N	Note 1
Other (Urology)	N	N	N			N	Note 1

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M;

Note 1: This feature does not use contrast agent.

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110999

Diagnostic Ultrasound Indications for Use Form

DUS 60 with C363UA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N	N			N	Note 1
Abdominal	N	N	N			N	Note 1
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N	N			N	Note 1

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional comments: Combined mode: B+M;

Note 1: This feature does not use contrast agent.

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110999

Diagnostic Ultrasound Indications for Use Form

DUS 60 with C362UA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N	N			N	Note 1
Abdominal	N	N	N			N	Note 1
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N	N			N	Note 1

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Additional comments: Combined mode: B+M;

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Mary S. Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110999

Diagnostic Ultrasound Indications for Use Form

DUS 60 with C343UA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N	N			N	Note 1
Abdominal	N	N	N			N	Note 1
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N	N			N	Note 1

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Additional comments: Combined mode: B+M;

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110999

Diagnostic Ultrasound Indications for Use Form

DUS 60 with C321UA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify)							
Neonatal Cephalic	N	N	N			N	Note 1
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Cardiac	N	N	N			N	Note 1
Intravascular							
Peripheral vascular							
Other (Urology)	N	N	N			N	Note 1

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Additional comments: Combined mode: B+M;

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

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Diagnostic Ultrasound Indications for Use Form

DUS 60 with L743UA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)	N	N	N			N	Note 1
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (**Conventional**)	N	N	N			N	Note 1
Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1
Intravascular							
Cardiac							
Intravascular							
Peripheral vascular	N	N	N			N	Note 1
Other (Urology)							

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

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Diagnostic Ultrasound Indications for Use Form

DUS 60 with L742UA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)	N	N	N			N	Note 1
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (**Conventional**)	N	N	N			N	Note 1
Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1
Intravascular							
Cardiac							
Intravascular							
Peripheral vascular	N	N	N			N	Note 1
Other (Urology)							

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Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110999

Diagnostic Ultrasound Indications for Use Form

DUS 60 with L763UA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)	N	N	N			N	Note 1
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (**Conventional**)	N	N	N			N	Note 1
Musculo-skeletal (**Superficial**)	N	N	N			N	Note 1
Intravascular							
Cardiac							
Intravascular							
Peripheral vascular	N	N	N			N	Note 1
Other (Urology)							

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110999

Diagnostic Ultrasound Indications for Use Form

DUS 60 with E743UA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal	N	N	N			N	Note 1
Transvaginal							
Transurethral							
Musculo-skeletal (**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)	N	N	N			N	Note 1

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110999

Diagnostic Ultrasound Indications for Use Form

DUS 60 with E613UA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal	N	N	N			N	Note 1
Transurethral							
Musculo-skeletal (**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)							

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K110999

Diagnostic Ultrasound Indications for Use Form

DUS 60 with C613UA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric	N	N	N			N	Note 1
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Cardiac	N	N	N			N	Note 1
Intravascular							
Peripheral vascular							
Other (Urology)							

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